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| EXAMINER | |
|---|---|
| PEPITONE, MICHAEL F | |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/584,115 | BROWN, MALCOLM | |
| | Examiner | Art Unit | |
| | MICHAEL PEPITONE | 1796 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *30 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-27 and 29-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27 and 29-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 June 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/4/10, 7/13/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10, 12-14, 16-19, 25-26, and 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brocchini *et al.* (US 2002/0082362) as applied to claim 1 above, in further view of Neuenschwander *et al.* (US 5,665,831).

Regarding claims 1-2, 7-10, 12-13, and 16: Brocchini *et al.* teaches a biodegradable polyacetal polymer (abstract; ¶ 3, 16-20), wherein of polymer of Formula (I) (¶ 63-81); is prepared by reacting a diol of Formula (II) with a divinyl ether of Formula (III) (¶ 82-86); wherein the diol of Formula (II) is a polyethylene glycol or polypropylene glycol having a molecular weight in the range of 100-20,000, most preferably 200-5,000, in particular a polyethylene glycol having a molecular weight of approximately 200-4,000 (¶ 91). Brocchini *et al.* (US '362) disclose Formula (I) containing polyamides (¶ 74-78). Brocchini *et al.* teaches a specific embodiment (ex. 1; polyacetal 3) comprising the reaction of poly(ethylene glycol) {mw = 3,400 g/mol} with tri(ethylene glycol) divinyl ether in the presence of *p*-toluenesulfonic acid (¶ 151-153) [see ex. 7 as well (¶ 169-178)]. Brocchini *et al.* teaches the diol may also comprise any diol suitable for use in biomaterials (¶ 91).

Brocchini *et al.* does not a specific diol comprising polyesters. However, Neuenschwander *et al.* teaches biocompatible block copolymers (abstract) comprising macrodiols based on α,ω-dihydroxypolyethers and α,ω-dihydroxypolyesters (2:9-20), wherein the macrodiols based on α,ω-dihydroxypolyesters are obtained by ring opening polymerization of lactones {dilactide, diglycolide, ε-caprolactone} (2:26-41; see examples). Neuenschwander *et al.* teaches the molecular weight of the macrodiol of about 300 to 10,000 daltons (2:43-54), and the resulting copolymer can contain a conjugate antibiotic (9:25-31). Brocchini *et al.* and Neuenschwander *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the preparation of biocompatible block copolymers containing conjugate bioactive compounds prepared from (macro)diols. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined α,ω-dihydroxypolyesters obtained by ring opening polymerization of lactones {dilactide, diglycolide, ε-caprolactone}, (2:26-41) having molecular weights of about 300 to 10,000 daltons, as taught by Neuenschwander *et al.* in the invention of Brocchini *et al.*, and would have been motivated to do so since Neuenschwander *et al.* suggests that α,ω-dihydroxypolyethers and α,ω-dihydroxypolyesters are equivalent macrodiols (2:9-20) [see MPEP 2144.06].

Regarding claim 3: Brocchini *et al.* teaches a specific embodiment (ex. 5; ¶ 161-166) comprising the reaction of poly(ethylene glycol) {mw = 3,400 g/mol} with an amino functionalized bis-vinyl ether monomer {containing a diamide bond (diamino acid ester)} (compound 11; ¶ 161-164) in the presence of *p*-toluenesulfonic acid (¶ 165-166).

Regarding claim 4-5, 18, 29-32: Brocchini *et al.* teaches a specific embodiment (ex. 6; ¶ 167-168) comprising the reaction of poly(ethylene glycol) {mw = 3,400 g/mol} with an achiral

bis-vinyl ether monomer having a conjugate bioactive compound (compound 16; ¶ 96-106, 167) in the presence of *p*-toluenesulfonic acid (¶ 165-166) {the as synthesized polymer-drug conjugate is a medical device}. Brocchini *et al.* teaches the polymer-drug conjugate as a pill/tablet, or contained in a carrier {coated medical device}.

Regarding claims 6, 14, 17, 19, and 25-26: Brocchini *et al.* teaches the polymer-drug conjugate of the invention (¶ 109, 112, 167-168) can be combined with preserving agents (¶ 110), pharmaceutically acceptable liquid carriers (¶ 112) and excipients such as polysacchrides and sodium chloride (¶ 115).

Brocchini *et al.* does not teach a specific embodiment comprising the polymer-drug conjugate of the invention (¶ 112, 167-168) combined with preserving agents, pharmaceutically acceptable liquid carriers, such as aqueous dextrose and glycols, or excipients such as polysaccharides {starch} and sodium chloride. However, at the time of invention a person of ordinary skill in the art would have found it obvious to have prepared the polymer-drug conjugate with preserving agents, pharmaceutically acceptable liquid carriers, such as aqueous dextrose and glycols, or excipients such as polysaccharides {starch} and sodium chloride based on the invention of Brocchini *et al.*, and would have been motivated to do so since Brocchini *et al.* suggests that intravenous injectable composition can be prepared using preserving agents, pharmaceutically acceptable liquid carriers, such as aqueous dextrose and glycols (¶ 110, 112); and lyophilized or freeze dried compositions can be prepared using excipients such as polysaccharides {starch} and sodium chloride (¶ 115).

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brocchini *et al.* (US 2002/0082362) in view of Neuenschwander *et al.* (US 5,665,831), as applied to claim 1 above, in further view of Shalaby (US 6,503,991).

Regarding claim 11: Brocchini *et al.* and Neuenschwander *et al.* render the basic claimed composition obvious [as set forth above with respect to claim 1], wherein Brocchini *et al.* disclose the diol may also comprise any diol suitable for use in biomaterials (¶ 91).

Brocchini *et al.* does not a specific diol comprising a carbonate. However, Shalaby teaches biocompatible block copolymers (abstract) comprising a pre-polymer prepared from an alkanediol containing a carbonate linkage (1:61-2:3). Brocchini *et al.* and Shalaby are analogous art because they are concerned with a similar technical difficulty, namely the preparation of biocompatible block copolymers prepared from diols. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined a pre-polymer prepared from an alkanediol containing a carbonate linkage, as taught by Shalaby in the invention of Brocchini *et al.*, and would have been motivated to do so since Shalaby suggests that carbonate linkages provide biomedical articles having controlled absorption and reduced hydrolytic instability (2:34-42).

Claims 15, 25, 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brocchini *et al.* (US 2002/0082362) in view of Neuenschwander *et al.* (US 5,665,831), as applied to claims 1 and 14 above, in further view of Wise *et al.* (US 6,071,982).

Regarding claim 15, 25, 27: Brocchini *et al.* and Neuenschwander *et al.* render the basic claimed composition obvious [as set forth above with respect to claims 1 and 14], wherein the polymer-drug conjugate of the invention may also include buffers (¶ 112).

Brocchini *et al.* does not teach a specific buffer. However, Wise *et al.* teaches bioerodible polymers (abstract) comprising buffers such as calcium phosphate (5:21-59) and calcium phosphate fibers (6:58-59). Brocchini *et al.* and Wise *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the preparation of biodegradable polymers comprising buffers. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined calcium carbonate and/or calcium phosphate fibers as a buffer, as taught by Wise *et al.* in the invention of Brocchini *et al.*, and would have been motivated to do so since Wise *et al.* suggests that calcium carbonate and calcium phosphate counteracts the effects of irritation, inflammation, and swelling caused by acidic products generated upon hydrolysis within the body (5:21-39).

Claims 20 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brocchini *et al.* (US 2002/0082362) in view of Neuenschwander *et al.* (US 5,665,831), as applied to claim 19 above, in further view of Pathak *et al.* (US 6,923,986).

Regarding claims 20 and 22: Brocchini *et al.* and Neuenschwander *et al.* render the basic claimed composition obvious [as set forth above with respect to claim 19], wherein the composition can include additives such as antibiotics, antiseptics (¶ 112), bioactive agents {drugs}, and anticancer agents (¶99); as well as other additives (¶ 112).

Brocchini *et al.* does not teach growth factors or growth agents. However, Pathak *et al.* teaches biodegradable polymers for use in drug delivery and biomedical applications (1:16-18), wherein additives such as antibiotics, antivirals, drugs and growth factors can be used in the composition; with specific growth factors including fibroblast growth factor {FGF} (11:8-36) and bone morphogenetic protein {BMP} (11:37-59). Brocchini *et al.* and Pathak *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the preparation of biodegradable polymers comprising additives such as antibiotics. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined FGF and BMP, as taught by Pathak *et al.* in the invention of Brocchini *et al.*, and would have been motivated to do so since Pathak *et al.* suggests that additives such as FGF and BMP are suitable for use in biodegradable polymers for use in drug delivery and biomedical applications (11:8-36).

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brocchini *et al.* (US 2002/0082362) in view of Neuenschwander *et al.* (US 5,665,831), as applied to claim 19 above, in further view of Törmäla *et al.* (US 6,579,533).

Regarding claim 21: Brocchini *et al.* and Neuenschwander *et al.* render the basic claimed composition obvious [as set forth above with respect to claim 19], wherein the composition can include additives such as antibiotics, antiseptics (¶ 112), bioactive agents {drugs}, and anticancer agents and bioactive proteins (¶99); as well as other additives (¶ 112).

Brocchini *et al.* does not teach a specific antibiotic. However, Törmäla *et al.* teaches bioabsorbable polymers containing antibiotics for use biomedical applications (1:5-26), wherein

specific antibiotics include vancomycin (7:27-37). Brocchini *et al.* and Törmäla *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the preparation of biodegradable polymers comprising additives such as antibiotics. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined vancomycin, as taught by Törmäla *et al.* in the invention of Brocchini *et al.*, and would have been motivated to do so since Törmäla *et al.* suggests that the antibiotic vancomycin is suitable for use in biodegradable polymers for use biomedical applications (7:27-37).

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brocchini *et al.* (US 2002/0082362) in view of Neuenschwander *et al.* (US 5,665,831), as applied to claim 19 above, in further view of Uhrich (US 2002/0071822).

Regarding claim 23: Brocchini *et al.* and Neuenschwander *et al.* render the basic claimed composition obvious [as set forth above with respect to claim 19], wherein the polymer-drug conjugate contains doxorubicin (¶ 99, 104).

Brocchini *et al.* does not teach methotrexate. However, Uhrich teaches biocompatible/degradable polymers containing bioactive compounds (¶ 7), wherein specific bioactive compounds include doxorubicin and methotrexate (¶ 42). Brocchini *et al.* and Uhrich are analogous art because they are concerned with a similar technical difficulty, namely the preparation of biodegradable polymers comprising bioactive agents. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined methotrexate, as taught by Uhrich in the invention of Brocchini *et al.*, and would have been motivated to do so

since Uhrich suggests that doxorubicin and methotrexate are equivalent bioactive agents (¶ 42) [see MPEP 2144.06].

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brocchini *et al.* (US 2002/0082362) in view of Neuenschwander *et al.* (US 5,665,831), as applied to claim 19 above, in further view of Heller *et al.* (US 7,045,589).

Regarding claim 24: Brocchini *et al.* and Neuenschwander *et al.* render the basic claimed composition obvious [as set forth above with respect to claim 19], wherein the composition can include additives such as antibiotics, antiseptics (¶ 112), bioactive agents {drugs}, and anticancer agents and bioactive proteins (¶99); as well as other additives (¶ 112).

Brocchini *et al.* does not teach a pain killer. However, Heller *et al.* teaches biodegradable polymers (1:9-12; 5:3-16) containing active agents such as anti-inflammatory agents including ketorolac; and local anesthetics such as lidocaine and bupivacaine (8:22-67). Brocchini *et al.* and Heller *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the preparation of biodegradable polymers comprising active agents. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined anti-inflammatory agents including ketorolac; and local anesthetics such as lidocaine and bupivacaine, as taught by Heller *et al.* in the invention of Brocchini *et al.*, and would have been motivated to do so since Heller *et al.* suggests that such active agents are suitable for use in biodegradable polymers for use biomedical applications (5:3-16; 8:22-67).

***Response to Arguments***

Applicant's arguments filed 6/30/10 have been fully considered but they are not persuasive. The rejection of claims based upon Brocchini *et al.* (US 2002/0082362) and Neuenschwander *et al.* (US 5,665,831) is maintained for reason of record and the following response. Brocchini *et al.* (US '362) disclose biodegradable polyacetal polymer (abstract; ¶ 3, 16-20), wherein of polymer of Formula (I) (¶ 63-81) is prepared by reacting a diol of Formula (II) with a divinyl ether of Formula (III) (¶ 82-86). Brocchini *et al.* (US '362) disclose Formula (I) containing polyamides (¶ 74-78). Brocchini *et al.* (US '362) disclose a conjugate bioactive compound (compound 16; ¶ 96-106, 165-167). Brocchini *et al.* (US '362) disclose the diol may also comprise any diol suitable for use in biomaterials (¶ 91).

Neuenschwander *et al.* (US '831) disclose biocompatible block copolymers (abstract) comprising macrodiols based on α,ω-dihydroxypolyethers and α,ω-dihydroxypolyesters (2:9-20), wherein the macrodiols based on α,ω-dihydroxypolyesters are obtained by ring opening polymerization of lactones {dilactide, diglycolide, ε-caprolactone}(2:26-41; see examples). Neuenschwander *et al.* (US '831) teaches the copolymer can contain a conjugate antibiotic (9:25-31). Neuenschwander *et al.* (US '831) disclose the polymers are biodegradable (11:20-22).

As Brocchini *et al.* (US '362) disclose the diol may also comprise any diol suitable for use in biomaterials, and Neuenschwander *et al.* (US '831) disclose biocompatible block copolymers comprising macrodiols based on α,ω-dihydroxypolyethers and α,ω-dihydroxypolyesters, one having ordinary skill in the art would have been motivated to employ α,ω-dihydroxypolyesters as the diol in the composition of Brocchini *et al.* (US '362) because Brocchini *et al.* (US '362) suggest any diol suitable for use in biomaterials and Neuenschwander

*et al.* (US '831) disclose biocompatible block copolymers comprising macrodiols based on α,ω-dihydroxypolyesters.

In response to applicant's argument that Brocchini *et al.* (US '362) and Neuenschwander *et al.* (US '831) are nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Brocchini *et al.* (US '362) disclose biodegradable polyacetal polymer (abstract; ¶ 3, 16-20), wherein the composition can be a polymer-drug conjugate (¶ 23, 96-106, 167-168); and Neuenschwander *et al.* (US '831) teaches biodegradable (11:20-22) copolymers that can contain a conjugate antibiotic (9:25-31). Brocchini *et al.* (US '362) and Neuenschwander *et al.* (US '831) are analogous art because they are concerned with a similar technical difficulty, namely the preparation of biocompatible block copolymers containing conjugate bioactive compounds prepared from (macro)diols

In response to applicant's argument that there is no teaching, suggestion, or motivation to combine the references, the examiner recognizes that obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992), and *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 82 USPQ2d

1385 (2007). In this case, Neuenschwander *et al.* suggests that α,ω-dihydroxypolyethers and α,ω-dihydroxypolyesters are equivalent macrodiols (2:9-20) [see MPEP 2144.06].

Shalaby (US 6,503,991) was relied on for disclosing biocompatible block copolymers (abstract) comprising a pre-polymer prepared from an alkanediol containing a carbonate linkage (1:61-2:3). In response to applicant's argument that there is no teaching, suggestion, or motivation to combine the references, the examiner recognizes that obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992), and *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007). In this case, Shalaby (US '991) suggests that carbonate linkages provide biomedical articles having controlled absorption and reduced hydrolytic instability (2:34-42).

Wise *et al.* (US 6,071,982) was relied for disclosing bioerodible polymers (abstract) comprising buffers such as calcium phosphate (5:21-59) and calcium phosphate fibers (6:58-59), as calcium carbonate and calcium phosphate counteracts the effects of irritation, inflammation, and swelling caused by acidic products generated upon hydrolysis within the body (5:21-39).

## *Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### *Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL PEPITONE whose telephone number is (571)270-3299. The examiner can normally be reached on M-F, 7:30-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Eashoo can be reached on 571-272-1197. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Eashoo/ MFP
Supervisory Patent Examiner, Art Unit 1796 9-September-10